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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/236,939 | 01/25/99 | GODOWSKI | P P0854C1D4 |

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| EXAMINER | |
|---|---|
| ULM, J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1646 | 6 |

**DATE MAILED:** 01/31/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/236,939 | Baker et al. |
| **Examiner** | **Group Art Unit** |
| John Ulm | 1646 |

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) 26-30 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 26-30 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

1) Claims 26 to 30 are pending in the instant application.

2) The first sentence of the instant specification has been amended to claim benefit of priority under 35 U.S.C. § 120 from one or more previous applications. This amendment attempts to incorporate the content of one or more prior applications into the instant specification by reference. Whereas the claim for priority under 35 U.S.C. § 120 is proper and can be made at any point during the prosecution of a patent application, the incorporation of material by reference constitutes new matter whose entry is prohibited by 35 U.S.C. § 132. New material can only be introduced into an application if that material is contained in an amendment which has been filed concurrently with the application under 37 C.F.R. § 1.53 **and** wherein the amendment is referred to in the oath or declaration **filed therewith**. See M.P.E.P. 608.04(b). Applicant is required to cancel the new matter in the response to this Office action.

3) 37 C.F.R. § 1.84(U)(1) states that when partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must be identified by the same number followed by a capital letter. Figure 1 of the instant application, for example, is presented on six separate panels. The three sheets of drawings which are labeled " Figure 1A-1, 1A-2 and 1A-3" in the instant specification should be renumbered "Figures 1A, 1B and 1C". The three sheets of drawings which are labeled " Figure 1B-1, 1B-2 and 1B-3, which are clearly not intended to form one complete view with Figures 1A-1, 1A-2 and 1A-3, should be renumbered Figures 2A, 2B and 2C. All of the figures in the instant application should be renumbered accordingly. Applicant is reminded that once the drawings are changed to meet the

separate numbering requirement of 37 C.F.R. § 1.84(U)(1), Applicant is required to file an amendment to change the Brief Description of the Drawings and the rest of the specification accordingly. For example, there is no "Figure 1A" currently in the instant application even though references to a "Figure 1A" are made in the instant specification. Because "Figure 1" is divided into Figures 1A, 1B and 1C, the Brief Description and all references to this figure in the specification must refer to Figures 1A, 1B and/or 1C.

4) The instant specification does not comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. **For example**, the description on page 9 of the instant specification of Figures "1A" and "1B" and the text on pages 12 and 18 therein discuss specific sequences without employing the required sequence identifiers. Correction of the entire specification is required. See M.P.E.P. 2422.03.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5) Claims 26 to 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention and to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The text on page 12 of

the instant specification indicates that the term "HTPK6" encompasses "any polypeptide sequence that possesses a biological property of a naturally occurring polypeptide comprising the polypeptide sequence of Figure 2". The text at the top of page 15 expressly states that this term encompasses "rPTK of various animal species rabbit, rat, porcine, non-human primate, equine, murine and ovine rPTK an alleles and other naturally occurring variants of the forgoing". The claims, therefore potentially encompass a rather large genus of isolated nucleic acids encoding a large number of different polypeptides, both natural and manmade. The instant specification, however, only describes a single isolated nucleic acid encoding a single receptor tyrosine kinase which is of human origin and which comprises the amino acid sequence presented in SEQ ID NO:4 of the instant application. There is absolutely no description what so ever contained therein of an isolated nucleic acid which encodes a protein of rabbit, rat, porcine, non-human primate, equine, murine or ovine origin. In the decision of *The Regents of the University of California v. Eli Lilly and Company,* 43 USPQ2d 1398 (CAFC 1997), the court held that:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood , 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by

> structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

Because the instant specification does not identify those structural or physical properties which distinguish a rTPK of rabbit, rat, porcine, non-human primate, equine, murine or ovine origin from one another or from that single human rTPK which is described in the instant specification, Applicant has failed to meet the written description requirements of 35 USC 112, first paragraph, for the genus of nucleic acids currently claimed. *In re Clarke*, 148 USPQ 665, (CCPA 1966) held that;

> " It appears to be well settled that a single species can rarely, if ever, afford support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.21 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of a small genus such as halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably large number of reductions to practice would probably be necessary."

It is clear that the instant claims, which encompass a large genus of nucleic acids encoding a substantial number of different proteins, are not supported by a specification which describes a single isolated nucleic encoding only a single member of the claimed genus.

Further, the instant claims encompass a large number of nucleic acids encoding a vast number of non-naturally occurring proteins. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Because the instant specification does not identify those amino acid residues within SEQ ID NO:4 which are essential to the structural and functional integrity of a rTPK protein and those residues which are expendable or substitutable, an artisan can not alter even a single amino acid residue within that sequence an predict "by resort to known scientific law" whether the resulting protein will retain the structural and functional properties of a rTPK protein. In the absence of this guidance or even a single working example of an isolated nucleic acid encoding an intentionally modified rTPK protein an artisan would have to resort to a substantial amount of undue experimentation involving the insertional, deletional and substitutional analysis of over 900 amino acid residues before they could even begin to be able to produce an isolated nucleic acid encoding

a rTPK protein with any reasonable confidence that the modified protein encoded thereby will perform as disclosed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6) Claims 26 to 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6.1) Claims 26 to 30 are vague and indefinite in the recitation of the limitation "HTPK6 receptor protein tyrosine kinase". Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "HTPK6 receptor protein tyrosine kinase" an artisan can not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

6.2) Claim 27 is vague and indefinite because the limitation "stringent conditions" is conditional and the conditions under which this property is to be determined are not recited in the claim or the instant specification. The text in lines 7 to 18 on page 19 of the instant specification provides some conditions of hybridization but these conditions are expressly identified there as exemplary, not limiting.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7) Claims 26 to 30 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by the Johnson et al. publication (P.N.A.S. 90:5677-5681, Jun. 1993).

8) Claims 26 to 29 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by the Di Mardo et al. publication (J. Biol. Chem. 268:24290-24295, 15 Nov. 1993).

9) Claims 26 to 29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Gilardi-Hebenstreit et al. publication (Oncogene 7(12):2499-2506, 05 Dec. 1992).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10) Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over either of the Di Mardo et al. or Gilardi-Hebenstreit et al. publications cited above. This claim is drawn to a process of producing and recovering the receptor tyrosine kinase encoded by an isolated cDNA as described in either of these two publication prior to the time of the instant invention. Each of the Di Mardo et al. and Gilardi-Hebenstreit et al. publications described an isolated cDNA encoding a receptor tyrosine kinase protein ands the protein encoded thereby. These references do not

anticipate this claim because they did not describe the recombinant production of the receptor protein encoded by either of those cDNAs. Because each if these references disclosed that the cDNA described therein encoded a receptor tyrosine kinase protein an artisan would have found it *prima facie* obvious to have expressed either of those cDNAs in a recombinant host cell and to have recovered the protein encoded thereby by employing procedures which were old, well known and routine in the art of molecular biology at that time to facilitate the characterization of that protein at the molecular level.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached at (703) 308-4310.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800